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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/572,529

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Conrad L. Cowan

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EXAMINER

ULM, JOHN D

ART UNIT

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1649

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/572,529	Applicant(s) COWAN, CONRAD L.	
	Examiner John D. Ulm	Art Unit 1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 December 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 48-73 is/are pending in the application.
- 4a) Of the above claim(s) 48-60 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 61-73 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 March 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/15/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 48 to 73 are pending in the instant application.

Election/Restrictions

Claims 48 to 72 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 12 December of 2008. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Drawings

The instant specification does not comply with 37 C.F.R. § 1.84(U)(1), which states that partial views of a drawing which are intended to form one complete view, whether contained on one or several sheets, must be identified by the same number followed by a capital letter. Figure 2 of the instant application, for example, is presented on three separate panels. The three sheets of drawings which are labeled "Figure 2" in the instant specification should be renumbered "Figures 1A, 1B and 1C". Applicant is reminded that once the drawings are changed to meet the separate numbering requirement of 37 C.F.R. § 1.84(U)(1), Applicant is required to file an amendment to change the Brief Description of the Drawings and the rest of the specification accordingly. M.P.E.P. 601.01(g) states that "if the drawings show Figures 1A, 1B, and 1C and the brief description of the drawings refers only to Figure 1, this is an error in the specification which must be corrected".

Specification

The instant specification does not comply with 37 C.F.R. § 1.821(d) which requires a reference to a particular sequence identifier (SEQ ID NO:) be made in the specification and claims wherever a reference is made to that sequence. For example, the amino acid sequence "NPXXY" is referred to throughout the specification without employing a sequence identifier and the amino acid sequence "TTIST" is discussed in line 4 on page 16 without employing an identifier. Correction is required. See M.P.E.P. 2422.03.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 61 to 66 and 68 to 73 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description and enablement requirements. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention and in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. In so far as these claims are drawn to a method that employs a "conjugate associated with the desensitization pathway of" a G protein-coupled receptor, the only such compound that is described in the instant specification or the art of record that is capable of functioning in the context of the

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instant invention is a conjugate comprising an arrestin protein. No other functional conjugate is suggested or described by the instant specification or the prior art of record.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 61 to 73 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by the Barak et al. patent (5,891,646). Barak et al., in its entirety, described a method of detecting the activation of a G protein-coupled receptor (GPCR) in a cell by introducing into that cell an arrestin/green fluorescent protein (GFP) conjugate and measuring the translocation of GFP activity to the cell membrane upon agonist activation of the GPCR. The text in lines 19 to 28 in column 8 and in lines 34 to 47 in column 11 expressly taught the use of a cell expressing two or more different GPCRs in the method described therein.

In so far as claim 64 is limited to an epitope tag or an affinity label, the right lane in Figure 2 of Barak et al. shows that GFP is capable of functioning as an epitope tag.

With respect to the limitations of claim 69, the text in lines 10 to 14 in column 14 of Barak et al. expressly stated that “GPCRs suitable for use in the present methods are those in which agonist binding induces G protein-coupled receptor kinase (GRK) phosphorylation; translocation of arrestin from the cytosol of the cell to the cell

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membrane subsequently occurs”, “that virtually all members of the GPCR superfamily desensitize via this common mechanism” and that “examples of suitable types of GPCRs include but are not limited to beta and alpha adrenergic receptors; GPCRs binding neurotransmitters (such as dopamine); GPCRs binding hormones; the class of odorant receptors (taste, smell and chemotactic receptors as found in nasal mucosa and the tongue, and on sperm, egg, immune system cells and blood cells); the class of type II GPCRs including secretin, glucagon, and other digestive tract receptors; light-activated GPCRs (such as rhodopsin); and members of the type III family of GPCRs which include but are not limited to metabotropic glutamate receptors and GABA_B receptors”.

The limitation recited in claim 71 that “indication of GPCR agonist activity is translocation or localization of at least one conjugate to a vesicle, endosome, granule or pit” is not distinguishing because this activity was well known to be inherent to a number of the GPCRs identified by Barak et al., as shown by the text in paragraph 0058 of the instant application.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (571) 272-0880. The examiner can normally be reached on 9:00AM to 5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Jeffrey Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/John D. Ulm/
Primary Examiner, Art Unit 1649